NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

06 April 2017

Group Members:

Name	*Present*	*Notes*
Ms Hannah Chambers	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Mr Anthony Kane	Yes	
Ms Kim Kingan	Yes	
Mrs Diana Robbins	Yes	
Dr Mark Taylor	Yes	Chair
Mr Marc Taylor	Yes	
Ms Gillian Wells	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor
Professor Martin Severs (For Item 3.a. only)	Medical Director and Caldicott Guardian
Mr Stephen Robinson (For Items 5.a. – 5.d. only)	Corporate Secretary

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies were noted for the meeting.

The Chair noted that Dr Katie Harron, CAG Member, who is currently on a leave of absence, was listed as Key Investigator on application 17CAG0051. No further action was required; however, it was agreed to acknowledge this within the minutes.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State for Health Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 09 March 2017 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 09 March 2017 meeting applications.

3. ITEMS FOR CONSIDERATION

a. NHS Digital – Advice Request

An item was presented by Professor Martin Severs. This item would be recorded in separate minutes, to be established separately in conjunction with the HRA and the communications team.

4. NEW APPLICATIONS – Non-research

a. 17CAG0049 – Improving Access to Psychological Therapies for Long-Term Conditions and Medically Unexplained Symptoms Pathfinder Project

Context

Purpose of Application

This application from NHS England and the University of Surrey set out the purpose of a service evaluation of the Improving Access to Psychological Therapies for Long Term Conditions and Medically Unexplained Symptoms (IAPT LTC MUS) Pathfinder Project, which involved 15 psychological therapy teams across England which were selected to become Pathfinder sites for the project. The rollout of the project started on 01 April 2012 – Phase 1 ended in summer 2013 with 13 pathfinders selected to continue or a second year during a reduced second phase. The service evaluation was commissioned to provide evidence to inform service transformation to achieve improvement in access to psychological therapies, which in turn is expected to reduce the long-term costs for the NHS.

The original project aimed to broaden the benefits of talking therapies by extending them to people with physical long term conditions and/or medically unexplained symptoms, which are physical symptoms caused by psychological distress. People with long term physical health conditions such as diabetes, cardiovascular disease, or chronic obstructive pulmonary disease often have co-morbid mental health conditions. Compared with the general population, people with diabetes are twice as likely to suffer mental health problems, and those with COPD, are three times more likely. People with two or more long term conditions are seven times more likely to have depression. The overall aim of the IAPT LTC MUS Pathfinder Project was to improve access to psychological therapies for these client groups.

In order to establish the impact on healthcare utilisation in secondary care and to identify savings to the NHS, linkage of data collected and analysed as part of the pathfinders project with hospital episode statistics (HES) data held by NHS Digital will be undertaken as part of this proposal. The clinical outcomes data has already been analysed by the evaluation team (University of Surrey). Examination of these findings in the context of secondary healthcare utilisation will complete the evaluation.

The service evaluation aims to answer the following questions:

- Is there an optimal stepped care pathway for LTC/MUS patients?
- What evidence supports each part of the pathfinder's model of delivery?
- What core therapy competencies are required at each step of the pathway and by whom?
- What background and additional training is necessary at the different levels of step care?
- How cost-effective and efficient are the different models?
- Is there evidence of clinical efficacy and improvement in LTC/MUS condition and status, from providing talking therapies to people presenting with LTC/MUS?

NHS Digital via DAAG determined that the consent which was in place for the pathfinder project was insufficient to cover the data linkage required for the evaluation programme, which is why this application has been made to CAG.

A recommendation for class 1, 4 and 6 support was requested to cover activities as defined in the application.

Confidential Patient Information Requested

The following items of confidential patient identifiable information will be transferred to NHS Digital to enable data linkage:

- NHS Number – for linkage,
- Postcode – for linkage and converted to CCG region for analysis,
- Date of birth – for linkage and returned as part of analysis data set as age at last birthday,
- GP practice code (these will be stripped after preparation of HES data extract),
- Pseudonymised ID – to enable the linkage at University of Surrey with raw data transferred direct from pathfinder sites.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application defined a clear medical purpose through the evaluation of a treatment pathway which could improve the care of a priority patient group, to understand whether the programme had been successful and was cost effective. It was agreed that the proposal was in the public interest as long-term conditions were a key focus in health care.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The CAG considered the feasibility of consent for this project and it was noted that returning to patients to seek further consent for the additional data linkage would not enhance the treatment pathways of the individuals. It was noted that the patient sample was known and contained approximately 5,000 patients, which was not an impossible cohort from which to seek consent. Members commented that at best, this would be a neutral process; however, it was agreed that there was potential for a detrimental impact to patients through revisiting this point in their care history after a break.

The applicants had provided examples of some of the historic participant information materials and consent documentation and it was agreed that these were inconsistent in terms of the level of detail provided around future data linkage.

Members also noted that further disclosure may be required to facilitate a consenting model than is currently requested in order to achieve the project aims.

The CAG agreed that support for the project would be recommended without the requirement for to seek further consent from patients on the condition that a meaningful system of patient notifications and opt-out model was devised for the programme.

- Use of Anonymised/Pseudonymised Data

The applicants are undertaking the programme analysis on a pseudonymised dataset; however, Members acknowledged that the required data linkage could not be undertaken without access to confidential patient identifiable information.

Justification of Identifiers

The CAG considered the identifiers requested to be justified to achieve the project aims.

Patient and Public Involvement and Engagement

Members discussed the information provided within the application and it was observed that the applicant was relying on the past involvement of patients as participants in the programme to satisfy involvement and engagement activities in relation to this application which was deemed inappropriate. The Group discussed the patient cohort which was the focus of the programme and it was acknowledged that as sufferers of long-term conditions, these patients were more likely to have maintained contact with health service providers. It was further commented that there was a wide support mechanism of patient groups in this area who could also be engaged with around the project.

The CAG agreed that the applicant should undertake some involvement and engagement activities and provide feedback around this before a recommendation of support could be reached. It was suggested that contact with relevant patient groups across the 15 providers who were involved in the initial project was appropriate to achieve meaningful engagement.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was described within the documentation that the applicants were relying on the historic opt-out arrangements which were in place for the original consented project as a dissent mechanism for this programme. Members discussed this and it was agreed that, having reviewed a selection of the historic information and consenting materials as part of this submission, there was little confidence that all participating patients were fully aware of the intended future data linkage required to evaluate the programme. As such, it was agreed that specific patient notification materials and mechanism of objection were required for the evaluation project.

The CAG agreed that the patient engagement and involvement activities which the applicants were required to undertake would provide a useful forum to discuss notifications and objections and seek guidance from patients to inform a suitable system could be operated in relation to this project. It was suggested that a mixed notification model be considered which did not rely solely on website publications.

Members agreed that evidence of an informed plan for patient notification and an objection mechanism would need to be reported back before a recommendation of support would be considered.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Patient and Public Involvement and Engagement :
a. Appropriate patient groups across the 15 pathfinder sites who were involved in the original project should be approached to inform the project,
b. These groups should be specifically engaged around what patient notification methods would be appropriate for the project and how a meaningful objection mechanism can be operated,
c. A report back on the activities which have been undertaken and their outputs is required for consideration.
2. Patient Notification and Objections:
a. Provide an overview of the informed plan for patient notifications and objections, including detail on how this will be implemented, together with copies of any documentation for consideration and clarification of how an objection mechanism will be respected.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the SofS will confirm approval. **Only at this point, if considered satisfactory, will a final approval outcome be issued and our Register of Approved Applications updated.**

Specific Conditions of Support

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - University of Surrey has a published reported grade of satisfactory at 75% on Version 14, 2016/17.)**

5. NEW APPLICATIONS – Research

a. 17CAG0047 – Long-Term Outcomes in Functional Neurological Symptoms in Children

Context

Purpose of Application

This application from the Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of the establishment of a research database into neurological symptoms in children. The applicants state that children and young people with functional symptoms will be identified from a database operating in the Newcastle paediatric neurology department since 1997. The identified patients' Newcastle hospital medical records will be examined to see to what extent their problems have persisted into adulthood and to try to identify factors associated with successful (symptom free) long term outcomes. The applicants will also perform a record-linkage study to identify involvement of the local NHS Trust that provides psychological and mental health services, to see whether involvement of these services has been associated with better long term outcomes.

This is a single purpose study and the assembled dataset will be destroyed after use. The topic of study is functional neurological symptoms - problems with abnormal movement, sensation, inability to move etc. with no conventional medical cause resulting from psychological factors. The project's aim is to identify long term outcomes after children present with functional neurological symptoms: whether their problems persist into adulthood.

A recommendation for class 4, 5 and 6 support was requested to cover activities as defined in the application.

Confidential Patient Information Requested

Access was requested to the following items of data for the project:

- NHS Number – data linkage,
- Hospital ID no
- Name – data linkage
- Last known address
- Date of birth – data linkage,
- Date of death,
- Postcode (clarified this is required at unit level)
- Gender,
- Health service district.

Cohort

The cohort will be established from an existing database containing 11,000 records and it was anticipated there will be approximately 120 individuals who would meet the inclusion criteria for the project.

Confidentiality Advisory Group Advice

Public Interest

Members considered the rationale put forward by the applicants around the potential public benefit which could be achieved from the proposal and concerns were raised which echoed the outstanding queries from the REC provisional opinion. The Group were unclear how the project would identify sufficient relevant data to achieve meaningful results to establish a public interest in supporting the application. The CAG advised that the outcome of the REC review was of interest to its considerations; assurance would be taken if the ethics committee were satisfied with the further rationale supplied by the applicant to support the public interest in the application.

Scope of the Project

The Group acknowledged that the applicant had erroneously included information within the application around entirely new presentations of functional symptoms in adult patients. It was highlighted that this information was not part of this application or the considerations which had been undertaken.

Identification of Patient Cohort

The CAG commented that the process to identify the relevant patient sample was not clear within the application; however, it was understood that the main applicant Dr Forsyth, who was considered a member of the direct care team, would identify the patient cohort through interrogation of the established clinical database with ICD10 codes. Confirmation was required that this was accurate and as such, outside the scope of the application for support under the Regulations.

Data Collection

The Group acknowledged from information within the advice form that a plan had not yet been finalised in relation to the data transfer and extraction arrangements with the NTW Trust, as the relevant approvals remained outstanding. However, Members stated that further information would be required around the individuals undertaking the data linkage and extraction before support could be recommended, to ensure these individuals had a lawful basis to access the patient records.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The CAG noted that the main applicant, Dr Forsyth, was part of the direct care team within the paediatric psychology department and had been responsible for the establishment of the clinical database from which the study sample would be taken. It was acknowledged that a preliminary review of this database had informed the approximate sample size of 120 patients to form the basis of this project.

From discussion of the project and the proposed design, the Group was not satisfied that consent was unfeasible for this patient cohort. It was noted that the sample size was limited and whilst the applicant's rationale around the potential for distress was acknowledged it was unclear why this patient group was particularly susceptible to distress that would override normal expectations about consent.

- Use of Anonymised/Pseudonymised Data

The Confidentiality Advice Team (CAT) raised queries in advance of the CAG meeting around the transfer and retention of confidential patient identifiable information. The CAG agreed that efforts should be made to reduce the identifiability of the dataset where possible. As such, any transfer of patient identifiers to the NTW Trust should be done so with a study identifier attached to enable any return data to be stripped of identifiable data. It was also agreed that the research dataset would need to be stripped of patient identifiers on completion of data linkage with relevant dates truncated as agreed by the applicant within the advice form.

Justification of Identifiers

Members considered the identifiers requested to be justified to achieve the data linkage required for the project aims; however, it was acknowledged that previous comments had been made around the requirement to reduce the identifiability of the dataset used for analysis.

Patient and Public Involvement

It is a key consideration of the CAG when recommending support to access and process identifiable patient information without consent that patient engagement has been undertaken to test the acceptability of using data for the prescribed project without consent. Whilst Members acknowledged the sensitivity around causing distress amongst patients and their family through the discussion of historic mental health issues, it was noted that the request for engagement did not relate to the specific patients whose data would be utilised in the project.

The Group commented that there were patient and parent support groups which could provide an appropriate source of engagement around the project to test the acceptability of undertaking this project without consent. It was agreed that the applicant would be required to undertake some appropriate activity around the proposal and provide feedback before a recommendation of support could be considered. The Group acknowledged that the applicant had identified some possible links for patient

involvement in the response to queries raised which could be utilised as a starting point for discussions; however, it was noted that more generic resources within the psychology and mental health fields could be approached.

Patient Notification and Objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The applicants had explained that attempts to notify specific individuals about the project presented a risk of real psychological harm to the individuals. The CAG considered the rationale provided; however, it was not noted there was a requirement to undertake meaningful notifications in relation to the project and offer an opt-out mechanism to any individual who raised an objection to their data being used for this purpose. Members suggested that valuable input could be achieved from engagement with patient groups around the most appropriate methods to achieve a meaningful notification and objection system in relation to this project. Response providing a detailed overview of how notifications and an opt-out mechanism could be achieved would need to be provided before consideration could be given to a recommendation of support under the Regulations.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further Information Required

The following information should be provided in the form of a revised application, together with a covering letter detailing response to all queries raised, to allow the CAG to continue their consideration of the application:

1. Provide further rationale to support the argument that consent is not feasible for the project.
2. The outcome of the REC review is required for consideration as the outstanding issues identified as part of its provisional opinion require resolution to provide assurance of the public interest in the application.
3. Confirmation is required around how the patient cohort would be established from the existing clinical database and who would be creating the research sample.
4. Clarification is required around the data linkage and extraction process which would be undertaken at the NTW Trust, to clarify whether the request for support under the Regulations would need to be extended to cover this activity.
5. The project should be redesigned to attach a study identifier to the patient data which is transferred between NHS Trusts, to enable the returned dataset to be pseudonymised against this reference in order to reduce the identifiability of the data being transferred.
6. Within the research dataset for analysis, patient identifiers should be stripped and key dates should be truncated to month and year format to reduce the identifiability of the information held.
7. Patient and Public Involvement and Engagement –
    a. Meaningful patient and public engagement should be undertaken to test the acceptability of using patient data without consent for the purposes defined in the application,
    b. The involvement and engagement activities should include discussion around how patient notifications and dissent mechanisms could be achieved for this patient group,
    c. A detailed report around the activities undertaken and planned should be provided for consideration.
8. Patient Notifications and Dissent –
    a. Provide detailed information around how a meaningful patient notification system could be operated for the project, together with an opt-out system and how this would be facilitated.

Once received, the information will be reviewed by a sub-committee of members in the first instance. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

b. 17CAG0050 – Educational Outcomes in Children Born After ART

Background

Under the memorandum of understanding established between the HFEA and the HRA, the CAG will consider and recommend to the Human Fertilisation and Embryology Authority (HFEA) whether to grant or refuse permission to use identifiable register information (or to impose conditions upon its use). As data controller of the Register, the HFEA will take a final decision based upon this recommendation, and then if disclosure is permitted will work with the applicant to enable use of the dataset. In terms of disclosure of confidential patient information not contained in the HFEA register, the CAG will advise under section 251 of the NHS Act 2006 and supporting Regulations in accordance with its standard operating procedures.

Context

Purpose of Application

This application from University College London Institute of Child Health set out the purpose of researching whether children born after assisted reproductive technology are at a higher risk of developing learning or behavioural problems. To date this question has not been adequately answered because existing studies have been small, and have not included adequate comparison groups.

This project proposed combining and analysing data from two existing large research databases: the Human Fertilisation and Embryology Authority (HFEA) Register and the National Pupil Database (NPD). Comparison of the educational and behavioural outcomes in children born following ART will be undertaken with two comparison groups of naturally conceived children. The project will make use of a previously established database of linked records from the Human Fertilisation and Embryology Authority (HFEA) and ONS data, for which support was recommended under application ECC 4-03(g)/2012. This application proposes to extend the use of this existing data to investigate educational outcomes in children born after ART.

Nearly 1 in 50 children in the UK are born to parents who have benefited from fertility treatments and this number is increasing year on year. Worldwide there are already over 5 million such children. The main applicant is a Paediatrician who has studied children born after assisted reproductive therapy (ART) and their families for over 20 years, and over this time, has developed insights into the concerns that these families have.

As the number of children born after ART is increasing, the need to monitor their long-term health and development becomes increasingly important. There are various reasons why the development of children born after ART may differ from naturally conceived children. Children born after ART are more likely to be born smaller in size, are more likely to be born premature, and are more likely to be born as part of a multiple birth (e.g. twins) when compared to naturally conceived children. These factors are known to have adverse effects on children's neurodevelopment. Furthermore, during ART embryos are exposed to unnatural environments and high doses of powerful hormones, which may have important effects on the developing embryo, including the brain. There is evidence that changes during this critical stage of early development can have long-term effects.

The applicants reference historic studies which have been undertaken in a similar area; however, it is explained that these were of limited scope and the methodology was questionable.

A recommendation for class 4 and 6 support was requested to cover activities as described in the application, in relation to the transfer of information from the established database held by NHS Digital

to the Department of Education, for linkage with the National Pupil Database. The request for support extends only to the transfer of patient identifiable information from NHS Digital to Department for Education and the transfer of linked-anonymised information from NHS Digital to University College London. Information from the National Pupil Database is outside the scope for support as this is not patient information.

It was acknowledged that the previously established database held by NHS Digital contained linked information from the Human Fertilisation and Embryology Authority (HFEA) Research Register and ONS. No further access was required to the HFEA Research Register for the project; however, an extension to the purpose of use of this data was recommended to the HFEA Research Register Panel.

Confidential Patient Information Requested

Cohort

The three cohorts to be compared in the study are as follows:

1. All children born in England following non-donor ART procedures recorded in the HFEA database between 1992 and September 2009.
2. Any naturally conceived siblings of these children will also be included and will form one of the control groups.
3. A second control group will consist of unrelated naturally conceived children, matched to a sample of the ART children. The inclusion criteria for this group will be that they have the same age and sex, and attend the same school, as the ART child to whom they are matched. This cohort will be identified by staff responsible for the NPD.

The applicant clarified that the cohort sizes for each group were as follows:

1. ART Children with educational outcome information – 60,000,
2. Naturally Conceived siblings of ART children – 6,000,
3. Unrelated children control cohort – 18,000.

The following items of confidential patient identifiable information are required for the purposes detailed:

- Name – linkage,
- Date of Birth – linkage and analysis (truncated to MM/YY format for analysis),
- Postcode (unit level) – required for socio-economic deprivation scoring calculation,
- Gender – linkage and analysis,
- Ethnicity – analysis,
- Unique study member number – for linkage of returned datasets.

With reference cohorts one and two identified above, this information is already held in an established database by NHS Digital. The database identifying cohorts one and two detailed above was established under study reference ECC 4-03(g)/2012. NHS Digital is the data controller for this established database.

This information will be utilised by staff at the Department for Education to create cohort three as detailed above; however, the identifiable information in relation to this cohort will be transferred in a pseudonymised format to researchers at University College London.

The applicants will also require access to parental infertility diagnosis and fertility treatment to enable stratification of these variables in secondary analysis.

Educational achievements will be ascertained by the outcomes of Key Stage Assessments. This information will be provided by the Department for Education through the linkage of patient records with the National Pupil Database.

NHS Digital will transfer confidential patient identifiable information to the Department for Education to enable linkage with the National Pupil Database. Support is requested to cover the this transfer of patient identifiers; however, it was noted that information returned from the Department of Education was outside the scope of support as this was not classed as patient information.

This application is to be considered separately to the existing application, ECC 4-03(g)/2012, which will continue. This application was submitted to cover an extension in purpose of the use of database which had been established under this previous approval.

The project is expected to run from 01/06/2017 through to 31/05/2019.

Confidentiality Advisory Group Advice

Public Interest

The Group discussed the application and agreed that this defined a clear medical purpose which was in the public interest as high-quality research was essential to understand whether or not this increasing population of children born following assisted reproduction therapy (ART) were at higher risk of developing learning or behavioural problems as they grow. This information would also enable individuals considering ART to receive appropriate and reliable information, and ensure that any problems in children can be identified and managed early.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The Group considered a number of arguments presented by the applicants to demonstrate that consent was not feasible. It was noted that the applicants would require access to additional data items which were not available from the source datasets in order to facilitate a consenting model and this would be more intrusive than the current project design. It was further noted that the project was not collating any health information, so there was potential for patients to have died or developed serious health conditions. As such, contact for consent would cause unnecessary and avoidable distress. Members were satisfied that the rationale was sufficient to make consent impractical for this project.

- Use of Anonymised/Pseudonymised Data

The applicants would undertake analysis on a pseudonymised dataset; however, there was a requirement to process confidential patient identifiable data items in order to achieve the required data linkage.

Justification of Identifiers

The CAG was satisfied that the identifiers requested were appropriate and proportionate to undertake the data linkage required to achieve the project aims.

Data Linkage

The CAG considered the comments from the grant reviewers which had been submitted to support the application. One of the reviewers had queried why the main data linkage stage of the project was expected to last eight months, with the required data cleaning and analysis anticipated extending a

further 12 months from this point. The Group acknowledged that this would allow the Department for Education access to the identifiable data for quite an extended period of time.

Members advised that further information was required to explain why the data linkage was expected to take so long. It was further queried whether the linkage file could be transferred to a trusted third party, like NHS Digital as example, whilst the data cleaning and analysis is being undertaken.

Patient and Public Involvement and Engagement

The Group acknowledged the level of patient and public involvement and engagement which had been achieved in the project design together with the support for the project which had been evidenced in documentation from relevant charities and support groups. Members requested that the public and patient engagement plans were extended throughout the undertaking of the project and it was agreed that a report should be provided at annual review providing an overview of actual and planned activities.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members acknowledged proposals for patient notifications put forward by the applicants which included promoting the study via the HFEA and Infertility UK websites, together with the newsletters of these organisations. These pathways would also be utilised to provide an opt-out mechanism to patients. The CAG agreed that these planned activities appeared appropriate. It was agreed that a report on the planned notification activities undertaken in line with the proposals put forward, with copies of documentation, should be included in the required for consideration at first annual review.

Security Assurance at the Department for Education

The Group acknowledged that the Department for Education (DfE) would be acting as data processor for the project. As a non-NHS government body, the DfE did not undertake the IG Toolkit. The CAT reported that in previous projects where linkage and processing had been undertaken by the DfE, a bespoke IG assessment had been undertaken by NHS Digital to provide assurance to the CAG around the data security arrangements and similar evidence was required in this instance.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Provide further information around why the required data linkage at the Department for Education was expected to take eight months.
2. It was understood that the pseudonymisation linkage key would need to be retained for 12 months following linkage, whilst data cleaning and analysis are undertaken. Consider the possibility of this linkage file being held by a third party. If this is not deemed feasible, provide strong rationale to support this.
3. Provide evidence that the Department for Education has appropriate security assurance in place.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Provisional Specific Conditions of Support

1. Patient and Public Involvement and Engagement – activity as specified should continue throughout the project and a report provided for consideration at first annual review around actual activities achieved and any further planned activities.
2. Patient Notification and Dissent – at first annual review, provide copies of patient notification materials in line with the planned activities, together with a report around the actual activity undertaken and an update on the management of patient objections.
3. Favourable opinion from a Research Ethics Committee. **(Confirmed – 08/03/2017)**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – UCL School of Life and Medical Sciences Data Safe Haven, Version 13, 2015/16, reported reviewed grade at 71% satisfactory, NHS Digital, Version 13, 2015/16, reported a reviewed grade at 91% satisfactory)**

c. 17CAG0051 – Head or Heart Study

Context

Purpose of Application

This application from University College London defined a research application which aimed to demonstrate the research potential of unconsented linkage between “dormant” (historical) trial data and administrative records for understanding long-term intervention effects. Through doing this, the applicants aim to evaluate the long-term safety and effects of giving nutritional supplementation in infancy on cognitive development. Data linkage is requested with HES (facilitated by NHS Digital) and the National Public Database (facilitated by the Department for Education), with initial referral to the NHS Patient Demographics service to complete the historic trial datasets with NHS numbers and addresses during school years to allow linkage with HES/NPD.

The cohort will be established from a unique series of eleven infant feeding trials with over 4,000 participants recruited between 1982 and 2001. The studies, which measured cognitive function at various points of follow up, struggled with low-response rates in later years, with retention as low as 12% by the age of 15 years., using conventional follow-up methods, it remains unclear whether the expected cognitive benefits sustain into adolescence and adulthood. Importantly, follow-up studies have also suggested that such interventions carry risks. As an example, in preterm infants nutrient-enriched diets that promote early growth were found to be associated with worse plasma lipid profiles and higher blood pressure in adolescence. The applicants explained that only a long-term follow-up of trial participants could address the unexamined balance between cognitive benefits and suggested potential metabolic harms.

The applicants advise that the historical trials did not seek consent for linkage with administrative data. Due to the limited quality and availability of administrative records, linkage to administrative data was not an option that was available to the investigators at the time of recruitment to those trials (between 1982 and 2001).

A recommendation for class 2, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

The following items of confidential patient information were requested:

- Name – linkage,
- NHS Number – linkage (only small number available),
- Date of birth – linkage and analysis,
- Date of death – analysis only
- Unit level postcode – linkage and deprivation score calculation,
- Gender – analysis,
- Ethnicity – analysis,
- Historical address details – linkage only.

The historic trials have a combined cohort of over 4,000 patients which will form the sample for study in this project.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application defined a clear medical purpose as it intended to follow-up on the findings of dormant historic trials, to understand whether nutritional supplements are beneficial or harmful to the development of infants. It was agreed that this had an important public interest.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The applicants argued that re-consenting participants from the historic trials which formed the patient cohort for this proposal was unfeasible. The CAG considered the information and it was agreed that the applicants would require access to additional data to facilitate a consented model for the project, as current address details would be required.

The applicants provided evidence in relation to a similar previous project which had attempted a re-consenting model. The applicants stated that in this instance, only 30% of participants provided further consent. Members were satisfied from the evidence supplied that in this instance, an attempt to seek new consent from the historic trial participants had the potential to bias the findings to the extent that the potential public benefit would be negated. The Group was satisfied that consent was not feasible for the proposal and recommendation for support under the Regulations would be required.

- Use of Anonymised/Pseudonymised data

The applicants would only undertake the project analysis on a pseudonymised dataset; however, it was acknowledged that processing of confidential patient information was necessary to enable the data linkage required to achieve the study outcomes. The data linkage activities had been designed in such a way to prevent each data processor involved in the project accessing any additional confidential patient identifiable data items that they did not already legitimately hold.

The CAG acknowledged that a linkage key to the pseudonymisation of participants would need to be retained whilst data analysis was being undertaken and it was queried whether this could be held by an external third party, like NHS Digital for example, to increase the security of the research dataset and consideration would be required by the applicants.

Justification of Identifiers

Members agreed that the requested identifiers were appropriate and proportionate to enable the required data linkage to be achieved.

Retention of Study Data

The Group recognised that the project had an anticipated duration of five years; however, the applicants were requesting retention of the data for 15 years. Members advised that further information was required from the applicants around the intended future plans for use of the data following the closure of the project, which would need to be provided at annual review.

Patient and Public Involvement and Engagement

The Committee acknowledged the engagement which had been undertaken with a sub-group of participants from the historical trials. It was agreed that additional engagement and involvement activities were required as the project progressed. This activity could be utilised to inform novel ways of achieving meaningful patient notifications for this patient cohort.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The applicants had advised that a study webpage had been set up on the UCL Institute for Child Health website to promote the project; however, Members agreed that further activity should be undertaken as the project progresses to improve and broaden the patient notification and dissent mechanism for the project.

Security Assurance at the Department for Education

The Group acknowledged that the Department for Education (DfE) would be acting as data processor for the project. As a non-NHS government body, the DfE did not undertake the IG Toolkit. The CAT reported that in previous projects where linkage and processing had been undertaken by the DfE, a bespoke IG assessment had been undertaken by NHS Digital to provide assurance to the CAG around the data security arrangements and similar evidence was required in this instance.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

4. It was understood that the pseudonymisation linkage key would need to be retained following linkage, whilst data cleaning and analysis are undertaken. Consider the possibility of this linkage file being held by a third party and provide response. If this is not deemed feasible, provide strong rationale to support this.
5. Provide evidence that the Department for Education has appropriate security assurance in place.

Once received, the information will be reviewed by the Chair in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support

1. It was acknowledged that the study data would be retained for 15 years following the closure of the study – at first annual review; provide further details around the future intentions for the study data to justify its onward retention for this duration.
2. Patient and Public Involvement and Engagement –
   a. Undertake additional patient and public involvement and engagement as the project progresses,
   b. Seek input around how the patient notifications and dissenting mechanism can be improved,
   c. Provide a report on actual and planned activity at first annual review.
3. Patent Notifications and Dissent –
   a. Improve and broaden the patient notification and dissent mechanisms as the project progresses,
   b. Provide a report, together with any notification materials developed, at first annual review on actual and planned activity at first annual.
4. Favourable opinion from a Research Ethics Committee. **(Confirmed – London City & East REC issued favourable opinion on 22 April 2017).**
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - UCL School of Life and Medical Sciences-Data Safe Haven, Version 13, 2015-16 reviewed reported grade at 71% satisfactory).**

d. 17CAG0058 – Research Using the National Chronic Kidney Disease Audit Data

Context

Purpose of Application

The National Chronic Kidney Disease Audit (NCKDA) collected between 2014-2016 data from 1057 general practices in England and Wales on testing of patients at risk of chronic kidney disease, as well as the identification and management of patients with chronic kidney disease. This non-research application is covered under reference CAG 6-07(c)/2013.

This current application requested support to allow the data to be used in future research of long term outcomes of audit participants after the audit ends, as otherwise the data would need to be deleted. The application requested support to transfer existing stored data which is currently held by Informatica. Anonymised clinical data will be stored at the London School of Hygiene & Tropical Medicine. Identifiable data (e.g. NHS numbers) will be stored separately in the secure data haven at the University College London. Future data on the outcomes (e.g. hospitalisations, deaths, heart disease, acute kidney problems in the context of other illness, complete kidney failure with need of dialysis) of patients who provided data for the audit will be collected by linking the NHS numbers to clinical records held in other databases in the coming years, thus forming a large cohort study on outcomes and health needs of patients at risk of or with chronic kidney disease in primary care.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities described in the application.

Confidential Patient Information Requested

The data set will include the following items of confidential patient information:

- NHS Number – to be stored at UCL separately from the clinical dataset, which will be held at LSHTM – to be used for data linkage,
- GP Practice Codes/CCG codes – to be stored at UCL and utilised to calculate deprivation scoring and undertake geographical analysis,
- Gender – retained to validate data linkage at LSHTM,
- Ethnicity – for analysis – to be stored at LSHTM.

The cohort is already established from the existing audit programme and contains data from 1,057 GP practices in England and Wales.

Confidentiality Advisory Group Advice

Public Interest

The Group confirmed that the application was in the public interest as it covered the retention of an extensive and very useful data set which had been established during the historic audit programme. The application had an ongoing medical purpose through the intended follow-up of patients included within the dataset over a further five years, to provide longer-term follow-up data, creating a more complete understanding of outcomes for this patient cohort.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of Consent

The CAG considered the practicality of attempting to seek subsequent consent for research purposes from the 6.5 million patients whose data was included in the current audit programme on a non-consented basis. Member supported the rationale that this was an unfeasible and disproportionate proposal and it was agreed that support would be recommended on a non-consented basis.

- Use of Anonymised/Pseudonymised Data

The applicants would be utilising a pseudonymised dataset for research purposes; however, retention of NHS number was required to facilitate data linkage for ongoing follow-up. Members recognised that the pseudonymised research database would be stored at the London School of Hygiene and Tropical Medicine and the decryption file was to be stored at University College London and were satisfied with this proposed separation.

Justification of Identifiers

The Group were satisfied that the requested identifiers were justified and proportionate to undertake the described activities.

Patient Involvement and Engagement

Members acknowledged the historic involvement activity which had been undertaken during the audit programme and it was also noted that the applicants had support from key renal charities for the proposed research database. It was commented that the purpose of the data use would change under this new application and the Group agreed that further involvement activity was required to promote the use of the dataset for research purposes. It was commented that the applicants could build on their established networks within related areas to facilitate this involvement and engagement.

It was recognised that the database covered patients from both England and Wales and Members suggested that engagement with the patients and the public could inform how to improve patient notifications and dissent mechanisms for Welsh patients.

The CAG considered the application and it was agreed that the applicants should supply a detailed plan of involvement and engagement activity to be undertaken as the project progressed at this stage for consideration. Reports could be provided at annual review around actual activities undertaken.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The Group considered the historic patient notification information which had been used to promote the audit programme and whilst it was agreed that this was still relevant, updates were required to highlight the change to research purposes. Members agreed that sight of updated website materials was required to ensure the content is appropriate.

It was recognised that Informatica, the current data processor within the audit programme, had accounted for all patient objections up to 2016, within the existing dataset.

The CAG also commented that improvements should be made to the notification and dissent system, to broaden this and offer in different mediums as it was accepted that not all patients would look for information on the internet. Members acknowledged that notification materials would need to take into account the stipulations of the Welsh Language Act. The Group agreed that the applicants could provide a report at first annual review around the improvements which had been made to the notification and dissent system.

Additional Points

The Confidentiality Advice Team (CAT) acknowledged that confirmation would be required from the applicants around the timeframe for data transfer to ensure support is in place under this new application for support whilst managing the closure of the existing audit application.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Patient and Public Involvement and Engagement –
   a. Provide a detailed plan of what public and patient engagement and involvement activities are planned to support the proposed research programmes,
   b. Consider how involvement and engagement from patients can improve notification and dissent mechanisms in Wales, taking into account the provisions of the Welsh Language Act.
2. Patient Notification and Dissent –
   a. Provide copies of revised website content for consideration, ensuring the background to the dataset and change to research purposes has been explained.

3. Clarify data transfer arrangements and timeframes from support which is covered under the existing audit application, confirming when the research database will be established.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support

1. Patient and Public Involvement and Engagement –
   a. Take forward the planned activities as provided in the detailed public and patient involvement and engagement plan,
   b. Provide a report at first annual review around actual activity undertaken, together with ongoing plans.
2. Patient Notification and Dissent –
   a. Improve and extend patient notifications and dissent options over the course of the project, accounting for the requirements of the Welsh Language Act,
   b. Provide a report at first annual review around progress which has been made in this progression, together with details of further plans.
3. Favourable opinion from a Research Ethics Committee. **(Confirmed – 03/03/2017)**
   Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – UCL School of Life and Medical Sciences Data Safe Haven report a reviewed satisfactory grade of 71% on Version 13, 2015-16)**

6. MINUTES OF THE MEETING HELD ON 09 MARCH 2017

The minutes were agreed as an accurate record.

7. CAG OFFICE REPORT

There were no items to report.

8. CAG CHAIR REPORT

There were no items to report.

9. ANY OTHER BUSINESS

No further business was noted.

The meeting was closed.